

June 18, 2006

TO: Laboratory Owners and Directors

FROM: Dennis P. McDonough, M.P.H., Director
Clinical Laboratory Improvement Service

SUBJECT: Re-adoption of N.J.A.C. 8:44 and N.J.A.C. 8:45

This is to advise you that the Department's Division of Public Health and Environmental Laboratories is proposing to readopt N.J.A.C. 8:44 and N.J.A.C. 8:45 without change. These rules govern the licensing and operation of clinical laboratories including licensing and proficiency testing fees and testing fees for the Department's Public Health Laboratory. The proposed re-adoptions will be published in the June 18, 2006 New Jersey Register for public comment at 38 N.J.R. 2560(a) and 38 N.J.R. 2564(a).

The Department is requesting to readopt these rules to ensure the continuation of rules governing clinical laboratories until such time as the Department approves proposed new rules for clinical laboratories developed by an Advisory Committee which will incorporate recent changes in federal regulations and will consolidate N.J.A.C. 8:44 and 8:45 into one chapter of rules for clinical laboratories. The proposed re-adoptions of N.J.A.C. 8:44 and N.J.A.C. 8:45 will allow the Department to continue to license, regulate, survey and enforce the rules for the licensing and operation of clinical laboratories until such time as the new rules are adopted.

Written comments on the proposed re-adoption of N.J.A.C. 8:44 and N.J.A.C. 8:45 must be postmarked no later than August 18, 2006 and should be submitted to:

Dennis P. McDonough, M.P.H., Director
Clinical Laboratory Improvement Service
Department of Health and Senior Services
Health and Agriculture Building, Room 405
P.O. Box 361
Trenton, N.J. 08625-0371
Fax: (609) 633-9601
E-Mail: dennis.mcdonough@doh.state.nj.us

The Department will convene a public hearing limited to the topic of the proposed re-adoption of N.J.A.C. 8:44 at 11:00 a.m. on Monday, July 10, 2006 at the New Jersey Department of Health and Senior Services, First Floor Auditorium, Health and Agriculture Building, 369 South Warren Street (at Market Street), Trenton, NJ 08608. Persons wishing to testify at the public hearing who wish to be placed on the list of speakers are requested to telephone Ms. Davis at (609) 292-9382 by Wednesday, July 5, 2006, and to bring an extra written copy of their remarks for submission to the public record.

Please contact the Clinical Laboratory Improvement Service at (609) 984-7923 if you have any questions. Thank you.